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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,106	REINHERZ ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *1-6,23-43 and 47-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-22 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Notice to Comply with Requirements for Sequence Disclosures.

DETAILED ACTION

Claims 1-53 are pending.

Election/Restrictions

1. Applicant's election of Group II, claims 7-22 and 44-46, in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-6, 23-43, 47-53 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 7-22 and 44-46 are being acted upon in this office action.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, Inventor Gerhard Wagner initialized but non-dated alteration to the zip code of the listed residence.

Specification

5. A) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Specifically, page 27, line 24 discloses an embedded hyperlink.

B)This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Sequences are disclosed in the specification that lack SEQ ID NO: tags, including page 16, lines 14 and 27, page 19, lines 8, 9 and 20, and page 20, line 26. Applicants are required to resubmit a substitute disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Drawings

6. It is noted that in the Brief Description of the Drawings Section of the specification, discloses that three drawingse xecuted in color are contained in the file. However, the examiner notes only black and white drawings. Clarification is required. Applicant is reminded that Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate. It is noted that the instant specification already contains the required first paragraph of the brief description of the drawings section of the specification stating:The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee" has been completed.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Objections

7. Claims 7-13 are objected to because of the following informalities: There is no article modifying the noun in the subject of each of said claims. Appropriate correction is required. Inserting the word "An" as the first word of each sentence is one way to overcome this rejection.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7-22 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 7-9, 14, 18 and 22 are indefinite in their recitation of the phrase "nucleic acid molecule which encodes", because it is not clear if closed language or open language is intended. For examination purposes, the claims are being interpreted with open language. Applicant is required to clarify.

B) Claim 8 is indefinite in its recitation of the phrase "substantial sequence identity" because the metes and bounds of said phrase are not clear and said phrase is not clearly defined in the specification. Applicant is required to clarify.

C) Claims 11-13, 15-17, 19-21 and 44-46 are indefinite in the recitation of the phrase "consisting essentially of a nucleotide sequence" recited in line 1 of claims 11, 12 and 13, and 44-46, because it is not clear if closed language or open language is intended. For examination purposes, the claims are being interpreted with open language. MPEP 2111.03 states that the transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Applicant is required to clarify. Claims 15-17 and 19-21 are included because they depend from claims 15-17 and 19-21.

D) Claims 11-13, 15-17 and 19-21 are indefinite in the recitation of the phrase "sequence encoding the amino acid sequence" recited in lines 1-2 of claims 11, 12 and 13, because it is not clear if closed language or open language is intended. For examination purposes, the claims are being interpreted with open language. Applicant is required to clarify. Claims 15-17 and 19-21 are included because they depend from claims 15-17 and 19-21.

E) Claims 12, 16, and 20 are indefinite in the recitation of SEQ ID NO:9. The instant specification discloses on page 5 that SEQ ID NO:9 is (GP[Y/F] XXXX[M/V]XXWXXXGYF. However, the sequence listing provided by applicant states that SEQ ID NO:9 is GPXXXXXXXXWXXXGYF, where X is any amino acid. Thus the amino acid sequence represented by SEQ ID NO:9 is not clear. Applicant is requested to clarify.

F) Claim 9 recites the limitation "endogenous gene" in line 2. There is insufficient antecedent basis for this limitation in the claim.

G) Claims 44-46 are indefinite in the recitation of the phrase "naturally comprise" because it is not clear what is encompassed by said phrase.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 7-9, 12—14, 16-18, 20-22 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 and dependent claims 8-9, 14, 18 and 22 are drawn to an isolated nucleic acid molecule which encodes a CD2BP2 protein, or an active derivative or fragment of said protein having CD2BP2 protein activity, or the complement of said nucleic acid molecule, a host cell comprising said nucleic acid molecule, and a method of producing said protein comprising said host cell. Claims 12-13, 16-17, 20 and 21 encompass an isolated nucleic acid molecule consisting essentially of SEQ ID NO:9 and SEQ ID NO:10, a nucleic acid construct comprising said sequence, and a recombinant host cell comprising said sequence.

A) The instant disclosure of an isolated nucleic acid molecule which encodes a CD2BP2 protein derived from human cells does not adequately describe the scope of the claimed genus of nucleic acid molecules which encode a CD2BP2, as recited in claims 7-9, 14, 18 and 22, which encompasses nucleic acid molecules which encode a CD2BP2 from a substantial variety of species. The specification does not describe a nucleic acid encoding a CD2BP2 protein from any species other than human, and therefore, the invention encompassing a nucleic acid encoding a CD2BP2 protein derived from all species is not adequately described. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

It is noted that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

B) However, the instant disclosure of the following fragments of a nucleotide encoding CD2BP2: (nucleotides encoding amino acids 129-341 of CD2BP2, nucleotides encoding encoding amino acids 225-341 of CD2BP2, nucleotides encoding encoding amino acids 256-341 of CD2BP2, nucleotides encoding encoding amino acids 256-338 of CD2BP2, and nucleotides

encoding encoding amino acids 291-317 of CD2BP2, (Page 22)), does not adequately describe the scope of the claimed genus of nucleic acid molecules which encode a fragment of CD2BP2 which has CD2BP2 protein activity as recited in claims 7-9, 14, 18 and 22, given the disclosed definitions of CD2BP2 activity and of biologically active fragments of CD2BP2 polypeptides.

The instant specification discloses on page 30, that biologically active fragments of CD2BP2 polypeptides encoded by nucleic acid molecules include any portion of the full length polypeptide which confers a biological function on the variant gene product, including ligand (CD2) binding and antibody binding. Page 28 discloses that activities of the encoded polypeptide include but are not limited to catalytic activity, binding function, antigenic function and oligomerization function. Page 59 of the specification discloses that a motif on CD2BP2 (SEQ ID NO:9 of SEQ ID NO:3) interacts with a motif on CD2 (SEQ ID NO:10). The human CD2 molecule is found on virtually all T cells and thymocytes and natural killer cells, and the CD2 cytoplasmic tail is important for T cell activation (page 2 of the specification).

However, with the exception of said fragments disclosed on page 22 which comprise said motif, the structure of "an isolated nucleic acid molecule which encodes a fragment of said protein having CD2BP2 protein activity" is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the of "an isolated nucleic acid molecule which encodes a fragment of said protein having CD2BP2 protein activity" encompassed by the claimed invention, especially in view of such a broad definition of CD2BP2 activity and in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes a fragment of said protein having said CD2BP2 protein activity. Therefore, with the exception of said fragments disclosed on page 22, there is insufficient written description for an isolated nucleic acid molecule which encodes a fragment of said protein having CD2BP2 protein activity.

C) Neither is there adequate written description for the an isolated nucleic acid molecule which encodes an active derivative of CD2BP2 that has CD2BP2 protein activity, as recited in claims 7-9, 14, 18 and 22, especially given such a broad definition of CD2BP2 activity and given the absence of a disclosure of a single such derivative. Page 28 discloses that nucleic acid molecules encoding derivatives which can be naturally occurring such as in the case of allelic derivatives, or non-naturally occuring resulting from mutagenesis, and include deletion, addition and substitution of one or more nucleotides which can result in conservative or non conservative amino acid changes, including additions and deletions, and also discloses that activities of the encoded polypeptide include, but are not limited to, catalytic activity, binding function, antigenic function and oligomerization function.

However, the structure of "an isolated nucleic acid molecule which encodes an active derivative of CD2BP2 that has CD2BP2 protein activity" is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the of "the an isolated nucleic acid molecule which encodes an active derivative of CD2BP2 that has CD2BP2 protein activity" encompassed by the claimed invention, especially in view of such a broad definition of CD2BP2 activity and in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes a derivative of said protein having said CD2BP2 protein activity. Therefore, there is insufficient

written description for an isolated nucleic acid molecule that encodes a derivative of said protein having CD2BP2 protein activity.

D) Neither is there adequate written description for the an isolated nucleic acid molecule which encodes a CD2BP2 protein derivative possessing substantial sequence identity with SEQ ID NO:2, as recited in claim 8, especially given a lack of a clear definition of the phrase "substantial sequence identity" in the instant specification, and given the absence of a disclosure of a single such derivative. Therefore, said derivative can encompass nucleic acid molecules comprising an indefinite number of deletions, additions and substitutions of one or more nucleotides which can result in innumerable conservative or non conservative amino acid substitutions and changes, including amino acid additions and deletions.

However, the structure of "an isolated nucleic acid molecule which encodes a CD2BP2 protein derivative possession substantial sequence identity with SEQ ID NO:2" is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the of "an isolated nucleic acid molecule which encodes a CD2BP2 protein derivative possession substantial sequence identity with SEQ ID NO:2" encompassed by the claimed invention, especially in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes said recited derivative of said protein having said CD2BP2 protein activity. Therefore, there is insufficient written description for an isolated nucleic acid molecule that encodes a CD2BP2 protein derivative possession substantial sequence identity with SEQ ID NO:2.

E) As noted in the 112 second paragraph rejections above, claims 7-9, 11-13, 15-17, 19-21 and 45-46 are being interpreted as open language of comprising. Since the claimed isolated nucleic acid molecule comprises a derivative or fragment of a CD2BP2 protein, as recited in claims 7-9, or comprises a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:9 (X nucleotides) or SEQ ID NO:10 (X nucleotides), as recited in claims 12-13 and dependent claims 16-17 and 20-21, said nucleic acid molecule can also encompass an indeterminate number and type of additional nucleotides, in addition to the nucleotides encoding the recited derivative or fragment or sequence. Since an indefinite number and type of additional nucleotides may also be encompassed by the recited nucleic acid molecule, the nucleic acid molecule of claims 7-9,11-13, 15-17 and 19-21 is not adequately described, especially given that the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify such a nucleic acid molecule.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*

12. Claims 7-9, 12-14, 16-18, 20-22 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule

which encodes a CD2BP2 protein, comprising SQ ID NO:1, 2, or 3, or a fragment of said protein having CD2BP2 protein activity, wherein said fragment consists of one of the following fragments of a nucleotide encoding CD2BP2: (nucleotides encoding amino acids 129-341 of CD2BP2, nucleotides encoding encoding amino acids 225-341 of CD2BP2, nucleotides encoding encoding amino acids 256-341 of CD2BP2, nucleotides encoding encoding amino acids 256-338 of CD2BP2, and nucleotides encoding encoding amino acids 291-317 of CD2BP2, (Page 22)), and the complement of said nucleic acid molecule, a host cell comprising said nucleic acid molecule, and a method of producing said protein comprising said host cell, an isolated nucleic acid molecule consisting of a nucleotide sequence consisting of SEQ ID NO:9, and 10, does not reasonably provide enablement for the broader recitation of an isolated nucleic acid molecule which encodes any CD2BP2 protein, any active derivative or fragment of CD2BP2 having CD2BP2 protein activity, or any derivative possessing substantial sequence identity with SEQ ID NO:2 as recited in claim 8, or any nucleic acid molecule consisting essentially of a nucleotide sequence encoding SEQ ID NO:9, and 10, as recited in claims 12-13 and encompassed by claims 16-17 and 20-21.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 7 and dependent claims 8-9, 14, 18 and 22 are drawn to an isolated nucleic acid molecule which encodes a CD2BP2 protein, or an active derivative or fragment of said protein having CD2BP2 protein activity, or the complement of said nucleic acid molecule, a host cell comprising said nucleic acid molecule, and a method of producing said protein comprising said host cell. Claims 12-13, 16-17, 20 and 21 encompass an isolated nucleic acid molecule consisting essentially of SEQ ID NO:9 and SEQ ID NO:10, a nucleic acid construct comprising said sequence, and a recombinant host cell comprising said sequence.

The instant spcification discloses that human CD2 molecule is found on virtually all T cells and thymocytes and natural killer cells, and the CD2 cytoplasmic tail is important for T cell activation (page 2 of the specification). And the mechanism by which the CD2t tail mediates activation is not clear. And that an intracellular protein termed CD2 binding protein 2 (CD2BP2) which binds a site containing two PPPGHR (seq ID NO:10) segments within the cytoplasmic region of CD2 has been described herein. , and that the CD2 binding region of CD2BP2 includes a 17 amino acid binding motif (SEQ ID NO:9) (GP[Y/F] XXXX[M/V]XXWXXXGYF which is also found in yeast and C. elegans proteins of unknown function(page 5 of the specification).

A) The instant disclosure of an isolated nucleic acid molecule which encodes a CD2BP2 protein derived ONLY from human cells does not provide sufficient guidance and direction regarding making any nucleic acid molecule which encodes a CD2BP2 protein derived from any species other than human as encompassed by claims 7-9, 14, 18 and 22. The state of the art does not teach any an isolated nucleic acid molecule which encodes a CD2BP2 protein, and therefore it would require undue experimentation for one of skill in the art to make an isolated nucleic acid molecule which encodes any CD2BP2 protein, other than one derived from human, of SEQ ID NO:1, without further guidance and direction from the specification.

B) The instant disclosure of the following fragments of a nucleotide encoding CD2BP2: (nucleotides encoding amino acids 129-341 of CD2BP2, nucleotides encoding encoding amino acids 225-341 of CD2BP2, nucleotides encoding encoding amino acids 256-341 of CD2BP2, nucleotides encoding encoding amino acids 256-338 of CD2BP2, and nucleotides encoding encoding amino acids 291-317 of CD2BP2, (Page 22)), does not provide sufficient guidance and direction regarding making a nucleic acid molecule which encodes any fragment of CD2BP2 which has CD2BP2 protein activity, as encompassed by claims 7-9, 14, 18 and 22, (except those disclosed supra), given the disclosed definitions of CD2BP2 activity and of biologically active fragments of CD2BP2 polypeptides, and the state of the art at the time the invention was made.

The instant specification discloses on page 30, that biologically active fragments of CD2BP2 polypeptides encoded by nucleic acid molecules include any portion of the full length polypeptide which confers a biological function on the variant gene product, including ligand (CD2) binding and antibody binding. Page 28 discloses that activities of the encoded polypeptide include but are not limited to catalytic activity, binding function, antigenic function and oligomerization function. Page 59 of the specification discloses that a motif on CD2BP2 (SEQ ID NO:9 of SEQ ID NO:3) interacts with a motif on CD2 (SEQ ID NO:10). The human CD2 molecule is found on virtually all T cells and thymocytes and natural killer cells, and the CD2 cytoplasmic tail is important for T cell activation (page 2 of the specification).

However, with the exception of said fragments disclosed on page 22 which comprise said motif (the 17 amino acid binding motif of CD2BP2(SEQ ID NO:9), the structure of an isolated nucleic acid molecule which encodes any fragment of said protein having CD2BP2 protein activity is not conventional in the art and therefore it would require undue experimentation for one of skill in the art to make an isolated nucleic acid molecule which encodes a fragment of said protein having CD2BP2 protein activity, encompassed by the claimed invention, without further guidance and direction from the specification, especially in view of such a broad definition of CD2BP2 activity and in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes a fragment of said protein having said CD2BP2 protein activity.

C) It would also require undue experimentation for one of skill in the art to make an isolated nucleic acid molecule which encodes any active derivative of CD2BP2 that has CD2BP2 protein activity, as encompassed by claims 7-9, 14, 18 and 22, especially given such a broad definition of CD2BP2 activity and given the absence of a disclosure of a single such derivative. Page 28 discloses that nucleic acid molecules encoding derivatives which can be naturally occurring such as in the case of allelic derivatives, or non-naturally occuring resulting from mutagenesis, and include deletion, addition and substitution of one or more nucleotides which can result in conservative or non conservative amino acid changes, including additions and deletions, and also discloses that activities of the encoded polypeptide include, but are not limited to, catalytic activity, binding function, antigenic function and oligomerization function.

However, the structure of an isolated nucleic acid molecule which encodes any active derivative of CD2BP2 that has CD2BP2 protein activity is not conventional in the art and therefore it would require undue experimentation for one of skill in the art to make an isolated

nucleic acid molecule which encodes any active derivative of CD2BP2 that has CD2BP2 protein activity encompassed by the claimed invention, without further guidance and direction from the specification, especially in view of such a broad definition of CD2BP2 activity and in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes a derivative of said protein having said CD2BP2 protein activity.

D) It would also require undue experimentation for one of skill in the art to make an isolated nucleic acid molecule which encodes any CD2BP2 protein derivative possessing substantial sequence identity with SEQ ID NO:2, as recited in claim 8, especially given a lack of a clear definition of the phrase "substantial sequence identity" in the instant specification, and given the absence of a disclosure of a single such derivative. Therefore, said derivative can encompass nucleic acid molecules comprising an indefinite number of deletions, additions and substitutions of one or more nucleotides which can result in innumerable conservative or non conservative amino acid substitutions and changes, including amino acid additions and deletions.

However, the structure of an isolated nucleic acid molecule which encodes any CD2BP2 protein derivative possession substantial sequence identity with SEQ ID NO:2 is not conventional in the art and therefore it would require undue experimentation for one of skill in the art to make an isolated nucleic acid molecule which encodes any CD2BP2 protein derivative possession substantial sequence identity with SEQ ID NO:2 encompassed by the claimed invention, without further guidance and direction from the specification, especially in view of the lack of a compensatory structural or correlative teachings in the prior art of an isolated nucleic acid molecule which encodes said recited derivative of said protein having said CD2BP2 protein activity.

E) As noted in the 112 second paragraph rejections above, claims 7-9, 11-13, 15-17, 19-21 and 44-46 are being interpreted as open language of comprising. Since the claimed isolated nucleic acid molecule comprises a derivative or fragment of a CD2BP2 protein, as recited in claims 7-9, or comprises a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:9 (X nucleotides) or SEQ ID NO:10 (X nucleotides), as recited in claims 12-13 and dependent claims 16-17 and 20-21, said nucleic acid molecule can also encompass an indeterminate number and type of additional nucleotides, in addition to the nucleotides encoding the recited derivative or fragment or sequence. Since an indefinite number and type of additional nucleotides may also be encompassed by the recited nucleic acid molecule, it would require undue experimentation for one of skill in the art to make the nucleic acid molecule of claims 7-9,11-13, 15-17 and 19-21, without further guidance and direction from the specification, especially given that the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify such a nucleic acid molecule.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 13, 17, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Seed et al (PNAS 84(10):3365-3369 (1987)).

Seed et al teaches an isolated nucleic acid that encodes the amino acid sequence of CD2, which encompasses SEQ ID NO:10, which is part of CD2. Therefore, the referenced teachings anticipate the claimed invention.

As discussed in the 112 second paragraph rejection, the claim is being read with open language. MPEP 2111.03 states that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Using closed language would overcome this rejection.

15. Claims 12, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Percy C (submitted to the EMBL data Library on October 1996) as evidenced by NCBI blast search.

Percy teaches the nucleotide sequence derived from C. elegans, wherein nucleotides 19 which encompasses a nucleotide encoding the amino acid sequence of SEQ ID NO:9 (specifically residues 19-45 of the referenced encoded amino acid sequence. Therefore, the referenced teachings anticipate the claimed invention.

As discussed in the 112 second paragraph rejection, the claim is being read with open language. MPEP 2111.03 states that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Using closed language would overcome this rejection.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
January 27, 2003

Amy DeCloux
1-27-03